

## Remarks

### **Rejections of the claims**

In the November 19, 2010 Office Action, the Office stated that:

(a) claims 81-84, 89-90, and 95 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,397,591 to Kyle *et al.* (hereinafter Kyle);

(b) claims 81-90, 92-93, 95, 101, 106-108, and 112-113 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,698,244 to Barclay (hereinafter Barclay);

(c) claims 91, 94, 96, and 99 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Barclay;

(d) claims 97, 98, 100, and 109-111 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of Japanese Patent No. 2002-253140 and Japanese Patent No. 60110250; and

(e) claims 102-105 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of U.S. Patent No. 6,638,561 to Beudekar *et al.* (hereinafter Beudekar) and U.S. Patent No. 5,453,565 to Mawson (hereinafter Mawson).

These rejections are respectfully traversed.

### **(A) Claims 81-84, 89-90, and 95 were rejected under 35 U.S.C. §102(b) as being anticipated by Kyle**

Claims 81-84, 89-90, and 95 were rejected under 35 U.S.C. §102(b) as being anticipated by Kyle. Specifically, the Office stated that “Kyle *et al.* disclose a biomass of *C. cohnii* that contains 30-40% DHA being used for aquaculture such as fish. By using the biomass aquaculturally for fish, Kyle *et al.* has produced an ‘aquaculturally-raised’ fish or shrimp or oyster, as claimed, and meets claim 81.” See, page 2, paragraph 1, of the November 19, 2010 Office Action.

Applicants disagree that Kyle anticipates claim 81. As currently pending, claim 81 recites:

81. An aquaculturally-raised aquatic animal made by cultivating an aquatic animal with a feed, wherein the feed is vegetarian and comprises a combination of hydrolyzed plant protein and bacteria comprising a carotenoid; and microalgae comprising docosahexaenoic acid (DHA), wherein at least 1% by weight of the fat content of the feed is DHA, wherein the carotenoid is selected from the group consisting of lutein, zeaxanthin, and lycopene and derived from a source selected from the group consisting of marigold petals, Lycium Chinese Mill Berries, tomatoes, microalgae, diatoms, and bacteria, and wherein less than 50% of the total carotenoid content of the aquaculturally-raised aquatic animal is astaxanthin.

Kyle does not disclose a vegetarian feed that includes the combination as recited above, and as such, cannot anticipate said claim or any claims depending therefrom. Reconsideration and withdrawal of the 35 U.S.C. §102(b) rejection of claims 81-84, 89-90, and 95 in view of Kyle is respectfully requested.

**(B) Claims 81-90, 92-93, 95, 101, 106-108, and 112-113 were rejected under 35 U.S.C. §102(b) as being anticipated by Barclay**

The Office stated that claims 81-90, 92-93, 95, 101, 106-108, and 112-113 were rejected under 35 U.S.C. §102(b) as being anticipated by Barclay. Specifically, the Office stated that “Barclay is drawn to, as the title suggests, raising animals having high concentrations of Omega-3 fatty acids as shown at col. 2 and col. 4, which includes the fatty acids claimed at instant claim 82, by feeding harvested biomass from the genus *Thraustochytrium* (col. 3, line 14). See col. 5, line 5, lines 15, 20-24.” See, page 2, paragraph 2, of the November 19, 2010 Office Action.

Applicants vigorously disagree because the Barclay reference suffers from the same shortcomings as that of Kyle, wherein all the limitations of the claims are not disclosed, taught or suggested. As such, Barclay cannot be considered to be an anticipatory reference. Applicants request the withdrawal of this rejection under section 102(b).

**(C) Claims 91, 94, 96, and 99 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Barclay**

The Office rejected claims 91, 94, 96, and 99 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Barclay. Specifically, the Office stated that:

Barclay discloses feeding elevated levels of DHA in the form of whole biomass paste, but Barclay does not disclose the DHA content of the animal or shrimp as claimed in claims

91 and 94. **Since Barclay discloses the same biomass to the same animal, including shrimp, as claimed, it must be inherent that the DHA content is the same.**

Alternatively, the burden to find the DHA content of the aquacultured animals of Barclay (col. 5, lines 19-20) is being shifted to applicant because the Office does not have the resources to obtain and measure such DHA contents to the variety of animals shown by Barclay and/or animals encompassed by claim 91. See, page 3, paragraph 2, of the November 19, 2010 Office Action (emphasis added).

Applicants respectfully disagree with the Examiner. Barclay discloses that

[t]he whole cell biomass can be used directly as **a food additive** to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed. See, col. 7, lines 42-45, of Barclay (emphasis added).

As disclosed by Barclay, the biomass is used as a food additive and not as a replacement of the animal feed. By disclosing that the biomass is **only a food additive**, it is impossible to determine the level of DHA in the aquatic animal. One does not know whether the additional feed contains animal material, whether it contains high or low levels of DHA, or whether the food additive is in addition to conventional feed. Animals cultivated using the feed of Barclay *may* result in a similar animal to what is claimed. This possibility, however, is insufficient to inherently anticipate the claimed aquatic animals. Inherency cannot be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Oelrich*, 212 USPQ 323 (CCPA 1981). Instead, it must consistently occur each and every time, which is necessary under case law to prove inherency.

Regarding the obviousness rejection, the Court's decision in *In re Spormann*, 150 USPQ 449 (CCPA 1966), bears directly on point:

“The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown”

As recited in MPEP §2112IV, “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art).” Hence, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*. Here the amount of DHA was

unknown. Therefore, how could a skilled artisan make any modification while arriving at an invention that possesses the heretofore unknown characteristic. While it is possible that, serendipitously, the feed would have such a feature, serendipity is not a valid basis for asserting obviousness. Thus, applicants submit that the Office has not met its burden of establishing a *prima facie* case of obviousness.

Reconsideration and withdrawal of the 35 U.S.C. §102(b) and/or 35 U.S.C. §103(a) rejection of claims 91, 94, 96, and 99 over Barclay is respectfully requested.

**(D) Claims 97, 98, 100, and 109-111 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of Japanese Patent No. 2002-253140 and Japanese Patent No. 60110250**

The Office rejected claims 97, 98, 100, and 109-111 under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of Japanese Patent No. 2003-0253140 and Japanese Patent No. 60110250. Specifically, the Office stated that “Barclay does not disclose taurine, but JP 2002-253140 discloses the use of carotenoids and taurine as feed for aquaculturally raised fish (see translation “farmed fish”).” See, page 4, lines 18-19, of the November 19, 2010 Office Action. The Office contends that it would have been obvious to include such ingredients already being used for the same purpose and to determine the amounts suitable for the type of animal. The Office includes Japanese Patent No. 60110250 in an attempt to teach that taurine provides resistance against various algae.

Applicants assert that Japanese Patent Nos. 2003-0253140 and 60110250 do not cure the deficiencies of Barclay with respect to independent claim 81, from which all claims depend. Namely, the Japanese patents do not teach cultivating an aquatic animal by using feed that is totally vegetarian. Instead, as clearly stated at the top of column 3 of the JP 2003-0253140, the feed included fish meal such as cuttlefish or krill. Thus, even if the JP secondary references teach the use of taurine, there is not sufficient disclosure for all the elements of claim 1 or to overcome the shortcomings of Barclay.

It is very important to note that applicants specifically included specific carotenoids from very specific sources because they did not want to add to the level of astaxanthin due to the negative effects of increased levels of astaxanthin as stated in paragraph [0033] of the published application. Applicants surprisingly found that the use of the sources, as recited in claim 81, did not result in complete conversion of the added carotenoids into astaxanthin. This is very important because the carotenoid level was increased but without the negative effects caused by increased levels of astaxanthin.

As previously stated, that which is unknown cannot possibly be obvious and none of the cited references recognize the importance of the specific sources of carotenoids. Thus, claims 97, 98, 100, and 109-111 distinguish over the prior art for at the least reasons discussed previously for distinguishing over Barclay. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 97, 98, 100, and 109-111.

**(E) Claims 102-105 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of Beudekar and Mawson.**

The Office rejected claims 102-105 under 35 U.S.C. §103(a) as being unpatentable over Barclay in view of Beudekar and Mawson. The Office included Beudekar and Mawson to allegedly teach that when microbial ARA rich feeds are used for aquaculturally-raised animals, carotenoids that are natural or artificial are included in the feed to improve pigment of the fish. Beudekar and Mawson, however, do not cure the deficiencies of Barclay as applied to independent claim 81. Mawson teaches the use of extra astaxanthin and this is exactly what applicants are trying to avoid, that being, increasing the level of astaxanthin because of the negative side effects of increased levels of astaxanthin. Beudekar teaches the use of ARA in the triglyceride form and the one statement at the top of column 5 that the diet may contain natural or artificial carotenoids is not sufficient to provide any guidance for applicants' discovery that certain natural carotenoids from specific sources do not completely convert to astaxanthin, thereby not increasing the levels of astaxanthin.

Applicants submit that the proposed combination does not establish a *prima facie* case of obviousness, and as such, reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of 102-105 is hereby requested

**Petition for Extension and Fees Payable**

Applicants petition for a one month extension and the fee of \$65.00 is being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

**Conclusion**

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Sayala,

reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Sayala is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

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